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A.0 510(k) Summary of Safety and Effectiveness

A.1 Submitter Information

OCT - 3 2008

Company Name and Address:	Contact Name:
Asahi Kasei Kuraray Medical Company, Ltd. 9-1, Kanda Mitoshirocho Chiyoda-ku, Tokyo 101-8482 Japan	David L. West, PhD, MPH Vice President, Medical Device Development 1801 Rockville Pike, Suite 300 Rockville, MD 20852 Telephone: 301-272-3113 Fax: 301-272-004 Email: david.west@quintiles.com

A.2 Date Prepared: August 29, 2008

A.3 Name of Device

3.1 Trade Name: Asahi REXEED-SX/LX Dialyzers

3.2 Common Name: High Flux Hemodialysis Membrane Dialyzer or High Flux Hollow Fiber Dialyzer

3.3 Classification Name, Class, Product Code and Panel

Classification Name and Regulation Number	Class	Product Code	Panel
High Permeability Hemodialysis Systems, Title 21 Code of Federal Regulations § 876.5860	II	KDI	Gastroenterology and Urology

A.4 Substantial Equivalence Claimed to Predicate Device

APS/REXEED, cleared for commercial distribution via 510(k) Premarket Notifications K001250 dated August 16, 2000; K041726 dated July 23, 2004; and K051187 dated June 8, 2005.

A.5 Device Description

The line of Asahi REXEED-SX/LX Dialyzers is a family of high permeability hollow fiber dialyzers intended for the treatment of patients with acute or chronic renal failure. REXEED-SX/LX Dialyzers are designed for single use. REXEED-SX/LX Dialyzers are constructed of hollow fiber (polysulfone) membranes, housed within a plastic casing of styrene-butadiene block copolymer and are subject to electron beam irradiation prior to shipment.

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This Special 510(k) describes the following modifications:

- Change in wall thickness of the polysulfone REXEED-SX/LX hollow fibers to 35 μm, compared to 45 μm for the existing predicate APS/REXEED
- Change in priming procedure to REXEED-SX/LX priming procedure (dry-type) from APS/REXEED priming procedure (wet-type)
- Change in sterilization type to electron beam irradiation REXEED-SX/LX Dialyzers, compared to gamma radiation for the existing predicate APS/REXEED
- Change in use to REXEED-SX/LX is available for single use from APS/REXEED which is available for single use and reuse.

A.6 **Intended Use and Indications for Use**

- REXEED-SX/LX Dialyzers is intended for use for hemodialysis treatment of patients who have chronic or acute renal failure.

- REXEED SX/LX Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.

- REXEED SX/LX Dialyzers have been tested *in vitro* under single use conditions.

A.7 **Evaluation of Design Modifications**

As the basis for Asahi Kasei Kuraray Medical's device evaluation studies and overall process for managing medical device risk, the company has performed a risk analysis using procedures based on ISO 14971(2000) "Medical Devices – Application of Risk Management to Medical Devices". The risk analysis method used to assess the impact of the modification was Failure Modes and Effects Analysis (FMEA). Design verification tests based on the result of risk analysis and design input were performed to verify those modifications. All test results meet the acceptance criteria, and proved that those modifications to be appropriate.

A.8 **Conclusion**:

Asahi Kasei Kuraray Medical made modifications to the original APS/REXEED cleared under K001250 K041726 and K051187, resulting in the REXEED-SX/LX Dialyzers. The information and data provided in this Special 510(k) Premarket Notification establish that the REXEED-SX/LX is substantially equivalent in intended use/indications for use, design, principle of operation, technology, materials, specifications, and performance to the existing unmodified APS/REXEED cleared under K001250, K041726 and K051187.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asahi Kasei Kuraray Medical Co., Ltd.
% David L. West, Ph.D., MPH
Vice President, Medical Device Development
Quintiles Consulting
1801 Rockville Pike, Suite 300
ROCKVILLE MD 20852

OCT - 3 2008

Re: K082515
Trade/Device Name: Asahi REXEED-SX/LX Dialyzers
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 29, 2008
Received: September 3, 2008

Dear Dr. West:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082515

6.0 Statement of Indications for Use

510(k) Number (if known): *Unknown*

Device Name: Asahi REXEED-SX/LX Dialyzers

Indications for Use:

A. REXEED-SX/LX Dialyzers is intended for use for hemodialysis treatment of patients who have chronic or acute renal failure.

B. REXEED SX/LX Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.

C. REXEED SX/LX Dialyzers have been tested *in vitro* under single use conditions.

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR § 801 Subpart D) (21 CFR §07 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082515